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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,949	07/10/2003	Lynn Kirkpatrick	126387.0120	4473

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EXAMINER	
KANTAMNENI, SHOBHA	
ART UNIT	PAPER NUMBER
1617	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/617,949	KIRKPATRICK ET AL.	
	Examiner	Art Unit	
	Shobha Kantamneni	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *10-27* is/are withdrawn from consideration.

5)☒ Claim(s) *NONE* is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/01/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-27 are pending, and examined herein.

Election/Restrictions

Claims 10-27 are withdrawn from consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions.

Applicant's election with traverse of invention Group I, drawn to a composition comprising asymmetric disulfide or derivative thereof and a matrix including at least one polymer, claims 1-9, in the reply filed on 11/14/2006 is acknowledged herein. The traversal is on-the grounds(s) that the search classification for each group will substantially overlap, and the examiner will not be seriously burdened by searching and considering the inventions. These arguments have been considered, but not found persuasive. The grouped inventions are patentably distinct, a reference which would anticipate, or make obvious, any inventions from groups I-II would not necessarily obviate or anticipate, the inventions in any other group. Although, the searches for the inventions maybe overlapping, the search for the inventions I-II is not co-extensive as indicated by the diverse nature of the subject matter. Thus, there is search burden, and examination burden on the office to examine both the groups.

The requirement is still deemed proper and is therefore made FINAL.

The Amendment received on 11/14/2006, wherein claims 10-27 have been withdrawn.

Claims 1-9 read on the elected invention, and examined herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-7 are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling for the particular asymmetric disulfides having recited functions such as "wherein the asymmetric disulfides is an inhibitor of cellular redox signaling", "wherein said asymmetric disulfide is an inhibitor of cellular redox signaling that prevents inhibition of apoptosis", "wherein said asymmetric disulfide is an inhibitor of thioredoxin or thioredoxin reductase" in the compositions therein, does not reasonably provide enablement for any compounds in general having functional properties recited in the claims herein in the compositions therein.

This recitations, an asymmetric disulfide which "is an inhibitor of cellular redox signaling", an asymmetric disulfide which "is an inhibitor of cellular redox signaling that prevents inhibition of apoptosis", and an asymmetric disulfide which "is an inhibitor of thioredoxin or thioredoxin reductase", are seen to be merely functions of asymmetric disulfide.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set

forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

The nature of the invention: The instant invention pertains to a composition, comprising any asymmetric disulfide having recited functions as discussed above.

The relative skill of those in the art: The relative skill of those in the art is high with respect to specific asymmetric disulfides having recited functions.

The breadth of the claims: The instant claims are deemed very broad since the claims read on any compounds having functional properties recited in the claims herein.

The amount of direction or guidance presented:

The guidance given by the specification as to what type of compounds have the recited functions is limited.

Functional language at the point of novelty, as herein employed by Applicants, is admonished in *University of California B. Eli Lilly* and Co. 43 USPQ2d 1398 (CAFC, 1997) at 1406: stating this usage does "little more than outline goal appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate". The CAFC further clearly states that "[A] written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition,

such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials" at 1405 (emphasis added), and that "It does not define any structural features commonly possessed by members of the genus that distinguish from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus.." at 1406 (emphases added).

In the instant case the recitations, an asymmetric disulfide which "is an inhibitor of cellular redox signaling", an asymmetric disulfide which "is an inhibitor of cellular redox signaling that prevents inhibition of apoptosis", and an asymmetric disulfide which "is an inhibitor of thioredoxin or thioredoxin reductase", recited are purely functional distinction. Hence, this functional recitation read on any unsymmetrical disulfides that might have the recited functions. The instant specification merely teaches (pages 26-27) that the unsymmetrical disulfide, 2-imidazoyl disulfide such as 1-methylpropyl 2-imidazolyl disulfide inhibits thioredoxin. Thus, the specification does not appear to be commensurate in scope with the instantly claimed genus having the recited functions.

Thus, Applicants functional language at the points of novelty fails to meet the requirements set forth under 35 U.S.C. 112, first paragraph. Claims employing functional language at the exact point of novelty, such as Applicants', neither provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limited of monopoly asserted" (Genera Electric Company v. Wabash Appliance Corporation et al. 37 USPQ at 468 (US Supreme Court 1938)).

The predictability or unpredictability: The instant claimed invention is highly unpredictable as discussed below:

The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genus. That is, the specification provides neither a representative number of compounds that encompass the genus of asymmetric disulfides having the claimed functions nor does it provide a description of structural features that are common to the asymmetric disulfides that have the recited functions. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure is insufficient to describe the genus. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art cannot fully describe genus, visualize or recognize the identity of the members of the genus, by structure, formula, or chemical name, of the claimed subject matter, as discussed above in *University of California B. Eli Lilly and Co.* Hence, in the absence of fully recognizing the identity of the members of genus herein, one of skill in the art would be unable to fully predict possible physiological activities of any compounds having claimed functional properties in the compositions herein.

The presence or absence of working examples and the quantity of experimentation necessary:

As discussed above, only those particular compound for each kind of functional compounds employed in the composition is disclosed in the specification. Thus, the evidence in the specification is not commensurate in scope with the claimed invention. See MPEP 716.02(d).

Thus, the specification fails to provide sufficient support of the broad use of any compounds having those functions recited in the instant claims. As a result, necessitating one of skill to perform an exhaustive search for the embodiments of any compounds having those functions recited in the instant claims suitable to practice the claimed invention.

Genentech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "asymmetric disulfide or the derivative thereof" in claim 1 is vague and indefinite, as it is not clear what compounds this term encompasses, and since one of ordinary skill in the art could not ascertain the metes and bounds as to "asymmetric disulfide or the derivative thereof". The specification recites that asymmetrical disulfides of the present invention have respective R groups of divergent functionality, and provides some examples of those groups. See page 4, paragraph [0021] of instant specification. However, it is not clear what other compounds are encompassed by the recitation because asymmetric disulfide can be any compounds having two different groups with divergent functionality attached to the disulfide.

Claim 3 is further rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites the limitation "said hydrophilic polymer" in claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, 4-9 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Powis et al. (Anti-Cancer Drugs 1996, 7 (suppl 3), pages 121-126, PTO-1449), and in view of Halperin et al. (US 5,633,274, PTO-1449).

Powis et al. disclose compounds such as 1-methylpropyl 2-imidazolyl disulfide, and benzyl 2-imidazolyl disulfide in a pharmaceutically acceptable carrier, for the use of thioredoxin reductase inhibition. See compounds IV-2 and DLK-36, page 124 of Powis. Powis et al. teaches a composition comprising 1-methylpropyl 2-imidazolyl disulfide. It is also taught that the alkyl 2-imidazolyl compounds, 1-methylpropyl 2-imidazolyl disulfide exhibits dose-dependent antitumor activity against human MCF-7 breast cancer xenografts growing. See page 124.

Powis et al. does not teach the employment of a polymer in the composition comprising asymmetric disulfide.

Powis et al. do not teach employment of another chemotherapeutic in the composition therein.

Halperin et al. teaches that active agents that inhibit cancer cell proliferation can be administered in a variety of formulations including sustained release delivery systems containing polymer matrix. It is also taught that the sustained release delivery systems include erosional systems in which the active agent is contained in a form within a matrix. See column 6, lines 1-30. It is also taught that the agents therein which inhibit cancer cell proliferation can be delivered in the form of anti-cancer cocktails with other anti-cancer agents or chemotherapeutic agent. See column 6, line 64-column 7,

line 25.

It would have been obvious to a person of ordinary skill in the art at the time of invention to employ 1-methylpropyl 2-imidazolyl disulfide in a polymer matrix because Halperin teaches that compounds that inhibit cancer cell proliferation can be administered in a variety of formulations which include entrapping in a polymer. One of ordinary skill in the art at the time of invention would have been motivated to employ asymmetric disulfide in a matrix comprising a polymer with the expectation of obtaining a sustained release delivery system that has the capability of releasing the active ingredient i.e asymmetric disulfide in a controlled rate.

It would have been obvious to a person of ordinary skill in the art to employ a chemotherapeutic agent in the composition comprising asymmetric disulfide. It is generally considered *prima facia* obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by recited teachings of Powis et al. and Halperin et al. the instant claims contain two compositions used for treatment of cancer i.e an asymmetric disulfide, and a chemotherapeutic agent. *In re Kerkohoven*, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

Furthermore, as the combined teachings of Powis et al., and Halperin et al. renders the claimed composition obvious, the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties, namely "wherein said composition erodes and releases the asymmetric disulfide", in claim 2,

are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product.

The recitations "wherein said asymmetric disulfide is an inhibitor of cellular redox signaling", and "wherein said inhibitor of cellular redox signaling prevents inhibition of apoptosis" here, are merely directed to the intended use of the claimed compounds, and does not limit the claims so long as the prior art discloses the same compounds. It is pointed out that the intended use of the compound must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. A composition is a composition irrespective of what its intended use is. See In re Tuominen, 213 USPQ 89 (CCPA 1982).

Claims 1-2, and 4-9 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Oblong et al. (Cancer Chemother. Pharmacol. 1994, 34: 434-438, PTO-1449), in view of Halperin et al. (US 5,633,274, PTO-1449).

Oblong et al. disclose compositions comprising asymmetric imidazolyl disulfides such as 1-methylpropyl 2-imidazolyl disulfide of the instant invention for the inhibition of cellular proliferation involving thioredoxin, thioredoxin reductase in an aqueous solution

which is a pharmaceutical carrier. See compounds IV-2 Fig. 1. Page 435. Employment of this compound in 0.2 M phosphate buffer is also disclosed. See page 435, right column, bottom paragraph, lines 4-6.

Oblong et al. does not teach the employment of a polymer in the composition comprising asymmetric disulfide.

Oblong et al. do not teach employment of another chemotherapeutic.

Halperin et al. teaches that active agents that inhibit cancer cell proliferation can be administered in a variety of formulations including sustained release delivery systems containing polymer matrix. It is also taught that the sustained release delivery systems include erosional systems in which the active agent is contained in a form within a matrix. See column 6, lines 1-30. It is also taught that the agents therein which inhibit cancer cell proliferation can be delivered in the form of anti-cancer cocktails with other anti-cancer agents or chemotherapeutic agent. See column 6, line 64-column 7, line 25.

It would have been obvious to a person of ordinary skill in the art at the time of invention to employ 1-methylpropyl 2-imidazolyl disulfide, an agent that inhibits cell proliferation according to Oblong et al. in a polymer matrix because Halperin teaches that compounds that inhibit cancer cell proliferation can be administered in a variety of formulations which include entrapping in a polymer. One of ordinary skill in the art at the time of invention would have been motivated to employ asymmetric disulfide in a matrix comprising a polymer with the expectation of obtaining a sustained release delivery

system that has the capability of releasing the active ingredient i.e asymmetric disulfide in a controlled rate.

It would have been obvious to a person of ordinary skill in the art to employ a chemotherapeutic agent in the composition comprising asymmetric disulfide. It is generally considered *prima facia* obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by recited teachings of Oblong et al. and Halperin et al. the instant claims contain two compositions used for treatment of cancer i.e an asymmetric disulfide, and a chemotherapeutic agent. *In re Kerkohoven*, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

Furthermore, as the combined teachings of Oblong et al., and Halperin et al. renders the claimed composition obvious, the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties, namely "wherein said composition erodes and releases the asymmetric disulfide", in claim 2, are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product.

The recitations "wherein said asymmetric disulfide is an inhibitor of cellular redox signaling", and "wherein said inhibitor of cellular redox signaling prevents inhibition of apoptosis" here, are merely directed to the intended use of the claimed compounds, and does not limit the claims so long as the prior art discloses the same compounds. It is pointed out that the intended use of the compound must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. A composition is a composition irrespective of what its intended use is. See In re Tuominen, 213 USPQ 89 (CCPA 1982).

Claim 3 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Powis et al. (Anti-Cancer Drugs 1996, 7 (suppl 3), pages 121-126, PTO-1449) or Oblong et al. (Cancer Chemother. Pharmacol. 1994, 34: 434-438, PTO-1449), and in view of Royer (US 5,783,214, PTO-892).

Powis et al., and Oblong et al. are applied as discussed in the above rejection.

Powis et al. or Oblong et al. do not teach the employment of a hydrophilic polymer in the composition comprising asymmetric disulfide.

Royer teaches sustained release delivery system comprising a gel matrix comprising hydrophilic polymer, gelatin for drugs which include anticancer drugs. It is taught that the delivery system therein provides easy control of release profile for drugs. See column 9, lines 16-20.

It would have been obvious to a person of ordinary skill in the art at the time of invention to employ 1-methylpropyl 2-imidazolyl disulfide, an agent that inhibits cell proliferation according to Powis et al. or Oblong et al. in a hydrophilic polymer matrix, gelatin because Royer teaches that anticancer drugs are incorporated into gel matrix which contains gelatin. One of ordinary skill in the art at the time of invention would have been motivated to employ asymmetric disulfide in a gel matrix comprising a hydrophilic polymer, gelatin with the expectation of obtaining a sustained release delivery system that has the capability of releasing the asymmetric disulfide in a controlled rate.

Claims 1-2, 4-7, and 9 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kirkpatrick et al. (Eur. J. Med. Chem 1992, 27, pages 33-37; PTO-1449), in view of Halperin et al. (US 5,633,274, PTO-1449).

Kirkpatrick et al. disclose compounds 1-methylpropyl 2-imidazolyl disulfide (IV-2) of the instant invention for the evaluation of selective cytotoxicity to hypoxic EMT6 tumor cells. See compounds 11, Table II. Page 34; page 35, right column, lines 1-3. Employment of this compound in 75 mL of 0.05 potassium phosphate buffer containing 0.1 M KCl is also disclosed. See page 37, left column, 2nd para from bottom.

Kirkpatrick et al. does not teach the employment of a polymer in the composition comprising disulfide.

Halperin et al. teaches that active agents that inhibit cancer cell proliferation can be administered in a variety of formulations including sustained release delivery

systems containing polymer matrix. It is also taught that the sustained release delivery systems include erosional systems in which the active agent is contained in a form within a matrix. See column 6, lines 1-30. It is also taught that the agents therein which inhibit cancer cell proliferation can be delivered in the form of anti-cancer cocktails with other anti-cancer agents or chemotherapeutic agent. See column 6, line 64-column 7, line 25.

It would have been obvious to a person of ordinary skill in the art at the time of invention to employ 1-methylpropyl 2-imidazolyl disulfide in a polymer matrix because Halperin teaches that compounds that inhibit cancer cell proliferation can be administered in a variety of formulations which include entrapping in a polymer. One of ordinary skill in the art at the time of invention would have been motivated to employ asymmetric disulfide in a matrix comprising a polymer with the expectation of obtaining a sustained release delivery system that has the capability of releasing the active ingredient i.e asymmetric disulfide in a controlled rate.

Furthermore, as the combined teachings of Kirkpatrick et al., and Halperin et al. renders the claimed composition obvious, the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties, namely "wherein said composition erodes and releases the asymmetric disulfide", in claim 2, are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior

art product does not possess or render obvious the same properties as the instantly claimed product.

The recitations "wherein said asymmetric disulfide is an inhibitor of cellular redox signaling", and "wherein said inhibitor of cellular redox signaling prevents inhibition of apoptosis" here, are merely directed to the intended use of the claimed compounds, and does not limit the claims so long as the prior art discloses the same compounds. It is pointed out that the intended use of the compound must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. A composition is a composition irrespective of what its intended use is. See In re Tuominen, 213 USPQ 89 (CCPA 1982).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8, 49, 52-60, 63-69, and 71 of copending Application No.10/366,751. Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of '751 are drawn to a composition comprised of a pharmacologically effective amount of a salt of 1-methylpropyl 2-imidazolyl disulfide and a pharmaceutically acceptable carrier, and 'instant claims are drawn to the composition comprising 1-methylpropyl 2-imidazolyl disulfide or a derivative thereof, and a matrix including a polymer.

It would be obvious to one of ordinary skill in the art to employ salt of 1-methylpropyl 2-imidazolyl disulfide as the derivative of 1-methylpropyl 2-imidazolyl disulfide. One of ordinary skill in the art would have been motivated to employ salt of 1-methylpropyl 2-imidazolyl disulfide with reasonable expectation of obtaining a composition effective as an inhibitor of cellular redox signaling. Further, a derivative of 1-methylpropyl 2-imidazolyl disulfide can include salts, and thus the instant claims and the composition claimed in the copending application '751 are substantially overlapping.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-9 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-10 of

copending Application No.10/600957. Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of '957 are drawn to a composition comprising 2-imidazolyl disulfide and a pharmaceutically acceptable carrier, and instant claims are drawn to a composition comprising asymmetric disulfide or a derivative thereof, and a matrix including a polymer.

It would be obvious to one of ordinary skill in the art to employ 2-imidazolyl disulfide as asymmetric disulfide or derivative thereof. One of ordinary skill in the art would have been motivated to employ 2-imidazolyl disulfide with reasonable expectation of obtaining a composition effective as an inhibitor of cellular redox signaling. Further, the species composition comprising a 2-imidazolyl disulfide that is useful in reducing or eliminating thioredoxin associated apoptosis inhibition claimed in the conflicting '957 application appears to fall within the same scope of the genus composition comprising an asymmetric disulfide or derivative thereof, wherein said asymmetric disulfide is an inhibition of thioredoxin or thioredoxin reductase claimed in the application being examined.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Tuesday-Thursday, 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, Ph.D can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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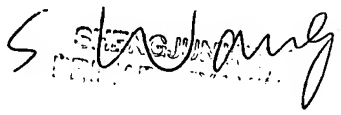

Shobha Kantamneni, Ph.D
Patent Examiner
Art Unit : 1617